

REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

Personal Interview

The undersigned gratefully acknowledges the courtesies extended to her by Examiner Kallis during the personal interview ("Interview") conducted on December 3, 2003. During the interview, the pending claims, potential claim amendments, and the GenBank situation were discussed.

Status

As is correctly indicated on the Office Action Summary, Claims 1-22 are pending. Claims 2-11, 13, 14, 16, 17, 19, and 20 have been withdrawn from consideration. Claims 1, 12, 15, 18, 21, and 22 stand rejected.

Summary of Amendments

By the foregoing amendments, Claim 1 was amended to recite specific high stringency conditions under which an isolated nucleic acid sequence hybridizes to the isolated nucleic acid sequence of Claim 1(a) and to recite "wherein said isolated nucleic acid sequence enhances expression of a structural gene located downstream of said isolated nucleic acid sequence." Support for these amendments may be found at least at Paragraphs

0026 and 0027 and Page 7, Lines 1-5, of the Specification. Accordingly, no new matter has been added.

Also by the foregoing amendments, Claims 15 and 18 were amended to delete language formerly rejected. *See Official Action mailed December 3, 2003, Page 7, ¶ 6.* Finally by the foregoing amendments, Claim 22 was amended to read "sequence identity" where "homology" had been recited. Support for this amendment may be found at least at Paragraph 0020 of the Specification. Accordingly, no new matter has been added.

Drawings

Form PTO 948 indicates that the Draftsperson objects to Figure 4 because the numbers and reference characters are not plain and legible and that the Examiner may require corrected drawings, if necessary.

Should the Examiner consider such correction necessary, Applicants again respectfully request an indication of any such necessity in the next communication.

Rejection Under 35 U.S.C. § 112, First Paragraph —Written Description

Claims 1, 12, 15, 18, 21, and 22 were rejected under 35 U.S.C. § 112, First Paragraph, as purportedly lacking sufficient written description. *See Official Action Pages 2-3.* According to the Examiner, Claims 1, 12, 15, 18, 21, and 22 lack sufficient written description because Claim 1 does not specify the degree of stringency. *Id.* This rejection is respectfully traversed.

"[I]psis verbis disclosure is not necessary to satisfy the written description requirement of section 112. Instead, the disclosure need only reasonably convey to persons

skilled in the art that the inventor had possession of the subject matter in question. . . . In other words, the question is whether [the instant] application provides adequate direction which reasonably would lead persons skilled in the art to the [claimed invention]." See *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570 (Fed. Cir. 1996). By the foregoing amendments, sole independent Claim 1 was amended to recite high stringency conditions ("at 65°C in a solution containing 5xSSC, 0.5% SDS, 5x Dernhardt's solution and 500µg/ml Salmon sperm DNA, followed by three washings for 15 minutes each at 25°C in 2xSSC and then three washings for 15 minutes each at 65°C in 2xSSC containing 0.1% SDS") and to include the recitation "wherein said isolated nucleic acid sequence enhances expression of a structural gene located downstream of said isolated nucleic acid sequence."

In light of the foregoing, Applicants maintain that one of skill in the art could readily determine that Applicants had possession of the isolated nucleic acid sequences set forth in Claim 1(c). Applicants respectfully request withdrawal of the 35 U.S.C. § 112, First Paragraph, rejection against Claims 1, 12, 15, 18, 21, and 22.

Rejection Under 35 U.S.C. § 112, First Paragraph —Enablement

Claims 1, 12, 15, 18, 21, and 22 were rejected under 35 U.S.C. § 112, First Paragraph, as purportedly not enabled. See *Official Action Page 3*. According to the Examiner, Claims 1, 12, 15, 18, 21, and 22 are not enabled because "undue experimentation would have been required to practice the claimed invention." *Id.* This rejection is respectfully traversed.

As discussed above, independent Claim 1 has been amended to recite specific high stringency conditions and to specify a test for a nucleotide sequence which falls within the

scope of the claims. In light of these amendments, one of skill in the art can readily screen for sequences which bind under the specified hybridization regimen. Following hybridization, one of skill in the art can then readily screen said sequences to determine, and then select, those that enhance expression of a structural gene located downstream thereto.

Because the foregoing *routine* experimentation does not constitute *undue* experimentation — the level of experimentation prohibited by the enablement requirement — Applicants respectfully request withdrawal of the 35 U.S.C. § 112, First Paragraph, enablement rejection against Claims 1, 12, 15, 18, 21, and 22.

Rejections Under 35 U.S.C. § 112, Second Paragraph — Indefiniteness

Claims 1, 12, 15, 18, 21, and 22 have been rejected under 35 U.S.C. § 112, Second Paragraph, as purportedly indefinite. *See Official Action Page 4*. This rejection is respectfully traversed.

With respect to Claim 1, as discussed above, "stringent conditions" have been specified using the information provided in Paragraphs 0026 and 0027 of the Specification. Accordingly, Applicants believe the instant amendments have rendered moot the indefiniteness rejection of Claim 1.

With respect to Claim 22, Applicants respectfully request clarification. The Examiner recommended that "an isolated nucleic sequence" in line 2 of Claim 22 be amended to read "the isolated nucleotide sequence." *See Official Action Page 4*. However, line 2 of Claim 22 reads "an isolated nucleic *acid* sequence." Moreover, Claim 22 references the isolated nucleic acid sequence of Claim 1.

Again with respect to Claim 22, the Examiner has asked that "homology" be amended to read "sequence identity." *See Official Action Page 4.* Applicants have made the recommended amendment.

In light of the foregoing, Applicants respectfully request withdrawal of the 35 U.S.C. § 112, Second Paragraph, indefiniteness rejection against Claims 1 and 22.

Rejections Under 35 U.S.C. § 102(b) and § 103(a)

The pending claims were rejected under 35 U.S.C. § 102(b) and 103(a) as purportedly anticipated by and made obvious by, in part, GenBank Accession Number AB026837 to H. Yang *et al.* ("Yang"). This rejection is respectfully traversed.

As discussed at the Interview, the effective date of Yang is the date on which it was published, December 19, 2000. Because Yang's publication occurred less than one year before Applicants' filing date, Yang is not an appropriate § 102(b) publication and may not be used in a § 103(a) rejection.

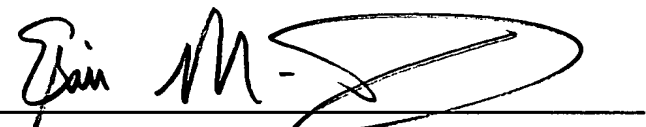
Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 102(b) and § 103(a) rejections against the pending claims.

CONCLUSION

From the foregoing, further and favorable consideration in the form of a Notice of Allowance is respectfully requested and earnestly solicited. However, should the Examiner disagree, Applicants have filed herewith a Notice of Appeal for all finally-rejected claims.

In the event that there are any questions relating to this response, or the application in general, it would be greatly appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,
BURNS, DOANE, SWECKER & MATHIS, L.L.P.

By: 
Erin M. Dunston
Registration No. 51,147

P.O. Box 1404
Alexandria, Virginia 22313-1404
(703) 836-6620

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